CASE 4-31830B

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

MALCOLM RICHARD BOYD

APPLICATION NO:

FILED:

FOR: NUCLEOSIDE ANALOGS IN COMBINATION THERAPY OF HERPES SIMPLEX INFECTIONS

Assistant Commissioner for Patents
Washington, D.C. 20231

PRELIMINARY AMENDMENT

Sir:

Prior to examination of this application, please amend the application as follows:

IN THE SPECIFICATION:

At page 1, after the title and before the first paragraph, please insert the following: -- This application is a continuation of Serial No. 09/117,154, filed on July 24, 1998.--

IN THE CLAIMS:

Please cancel claims 1-6 without prejudice.

Please add new claims 7 – 22 as follows:

7. A pharmaceutical composition comprising an effective amount of a nucleoside analogue active against herpes simplex virus selected from the group consisting of penciclovir and famciclovir, or a pharmaceutically acceptable salt or ester thereof and an effective amount of a pharmaceutically acceptable immunosuppressant.

8. A method of treatment or prophylaxis of herpes simplex virus infections in a human in need thereof, which method comprises administering to said human, an effective amount of a nucleoside analogue active against herpes simplex virus selected from the group consisting of penciclovir and famciclovir, or a pharmaceutically acceptable salt or ester thereof and an effective amount of a pharmaceutically acceptable immunosuppressant.

9. The composition according to claim 7 wherein the immunosuppressant is selected from the group consisting of a cytotoxic agent, a corticosteroid, and a non-steroidal anti-inflammatoryagent.

10. The composition according to claim 9, wherein the immunosuppressant is selected from the group consisting of cyclophosphamide, cyclosporin A, hydrocortisone, and dexamethasone.

11. The method according to claim 8, wherein the immunosuppressant is selected from the group consisting of a cytotoxic agent, a corticosteroid, and a non-steroidal anti-inflammatory agent.

12. The method according to claim 11, wherein the immunosuppressant is selected from the group consisting of cyclophosphamide, cyclosporin A, hydrocortisone, and dexamethasone.

13. A method of treatment or prophylaxis of a herpes simplex virus infection in a human in need thereof, which method comprises administering simultaneously to said human an effective amount of a nucleoside analogue active against herpes simplex virus selected from the group consisting of penciclovir and famciclovir, or a pharmaceutically acceptable salt or ester thereof and an effective amount of a pharmaceutically acceptable immunosuppressant.

14. The method according to claim 13, wherein the immunosuppressant is selected from the group consisting of a cytotoxic agent, a corticosteroid, and a non-steroidal anti-inflammatory agent.

15. The method according to claim 14, wherein the immunosuppressant is selected from the group consisting of cyclophosphamide, cyclosporin A, hydrocortisone, and dexamethasone.

16. A method of treatment or prophylaxis of herpes simplex virus infection in a human or animal in need thereof, which method comprises administering separately or sequentially to said human or animal an effective amount of a nucleoside analogue active against herpes simplex virus selected from the group consisting of penciclovir and famciclovir, or a pharmaceutically acceptable salt or ester thereof and an effective amount of a pharmaceutically acceptable immunosuppressant.

17. The method according to claim 16, wherein the immunosuppressant is selected from the group consisting of a cytotoxic agent, a corticosteroid, and a non-steroidal anti-inflammatory agent.

18. The method according to claim 17, wherein the immunosuppressant is selected from the group consisting of cyclophosphamide, cyclosporin A, hydrocortisone, and dexamethasone.

19. A pharmaceutical composition according to claim 7, wherein the composition is adapted for parenteral administration.

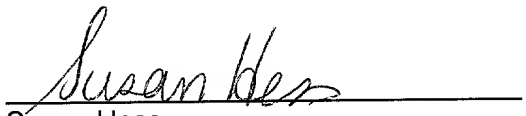
20. A pharmaceutical composition according to claim 7, wherein the composition is adapted for oral administration.

21. A method according to claim 8, wherein at least one of the nucleoside analogues or immunosuppressants is administered parenterally.

22. A method according to claim 8, wherein at least one of the nucleoside analogues or immunosuppressants is administered orally.

Applicant respectfully submits that the above claims are now in condition for allowance, which which action is earnestly solicited.

Respectfully submitted,



Susan Hess
Attorney for Applicant
Reg. No. 37,350

Novartis Corporation
Patent and Trademark Dept.
564 Morris Avenue
Summit, NJ 07901-1027
(908) 522-6938

Date: June 19, 2001